

CDER Breakthrough Therapy Products Approved in Calendar Year (CY) 2013

January 1, 2013 Through December 20, 2013

Application Number	Supplement Number	Proprietary Name	Established Name	Applicant	Approval Date
BLA 125486	N/A	GAZYVA	OBINUTUZUMAB	GENENTECH, INC.	11/1/2013
NDA 205552	N/A	IMBRUVICA	IBRUTINIB	PHARMACYCLICS, INC.	11/13/2013
NDA 204671	N/A	SOVALDI	SOFOSBUVIR	GILEAD SCIENCE, INC.	12/6/2013

